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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Judge Joel A. Pisano Magistrate Judge Tonianne J. Bongiovanni

HANMI'S OPPOSITION TO ASTRAZENECA'S MOTION *IN LIMINE* TO PRECLUDE RELIANCE ON EVIDENCE OF EXPERIMENTS PERFORMED BY MR. BRACKEEN FOR WHICH SAMPLES AND DOCUMENTATION HAVE NOT BEEN PRODUCED

AstraZeneca seeks to preclude Hanmi from offering at trial evidence of experiments performed by Mr. Marcus Brackeen replicating several examples described in the prior art Kohl reference (DE 455). AstraZeneca also seeks preclusion of other Hanmi experts from relying on Mr. Brackeen's work. AstraZeneca bases its motion *in limine* on the alleged refusal by Hanmi and Mr. Brackeen to produce "critical underlying documentation" and "samples" concerning the work in question.

But neither Hanmi nor Mr. Brackeen has refused to produce documentation or samples underlying the experiments subject to Mr. Brackeen's February 19 report; rather, as discussed in Section A below, Hanmi and Mr. Brackeen have produced all materials in their custody and control relied upon by Mr. Brackeen in preparing his February 19, 2013 report.

Moreover, the testimony and evidence in question constitutes reliable expert testimony as to Mr. Brackeen's own work, is entirely permissible, and will be helpful to the Court. Fed. R. Evid. 702. As discussed below, there is no basis to preclude Mr. Brackeen, Dr. Atwood or any other Hanmi expert from relying on Mr. Brackeen's experimental work.

Nor would AstraZeneca be prejudiced by introduction of the testimony and evidence. AstraZeneca has known of Mr. Brackeen's work for years and has offered multiple declarations in prior proceedings challenging Mr. Brackeen's testimony *based on the very same data Hanmi relies on in this case.* AstraZeneca has never stated in any other forum that it was unable to respond to the same data. Hanmi has relied on nothing new, and Dr. Davies has again already submitted two responsive reports in the present action. None of AstraZeneca's arguments provide a basis to preclude reliance on Mr. Brackeen's work. That AstraZeneca questions the veracity of Mr. Brackeen's testimony is not grounds for blanket exclusion to Hanmi's detriment; at most AstraZeneca's arguments go to the weight of the evidence, not its admissibility.

Finally, AstraZeneca's preclusion arguments are disingenuous, given that its papers and expert reports rely heavily upon the work of others as reported in similar declarations, as well as documentation and samples – none of which have been provided to Hanmi in this action despite Hanmi's discovery requests.

If the Court is inclined to preclude Hanmi's reliance on Mr. Brackeen's work based on absence of original samples and documentation concerning *other* projects, the same standard should be applied to AstraZeneca. Basic fairness demands that AstraZenenca not be permitted to rely on Declarations and testimony of Drs. Kohl and Dr. Larsson, who also replicated certain examples of the Kohl prior art reference. None of the underlying work or samples was provided to Hanmi. Nor should AstraZeneca's Dr. Davies be permitted to testify about the work of anyone who purportedly failed in attempting to replicate the examples of the Kohl reference.

A. Hanmi And Mr. Brackeen Have Produced All Materials Relied Upon By Mr. Brackeen In Their Custody And Control

Several years ago, Mr. Brackeen replicated Examples 4 and 5 of the DE' 455 prior art reference, successfully obtained products, and prepared a Declaration reporting his results. The Declaration and supporting data were submitted in European Opposition proceedings involving a counterpart patent to the '504 and '192 patents in suit here.[1] AstraZeneca responded to Mr. Brackeen's European Declaration by submitting a number of its own Declarations attempting to show Kohl's examples could not be successfully replicated. Those Declarations were authored by, *e.g.,* Dr. Kohl and Dr. Larsson, and Dr. Davies offered his own *meta*-

[1] The disclosure of DE '455, as well as the reproducibility of the methods disclosed therein – shown by Mr. Brackeen, and independently by others (Drs. Hornchen and Kirschning *see* Ex. 7-9), to produce the enantiomers of omeprazole having an optical purity greater than required by the patent claims (at least 94% enantiomeric excess (or "ee") and at least 98% ee) – were the subject of European Opposition Nos. 1020460 and 1020461. *See e.g.*, Reply Report of Jerry L. Atwood, dated April 8, 2013, ¶¶12-28, 55-59.

opinions commenting on the work of other declarants. All Declarations and exhibits became part of the European Opposition proceeding file, and all were – and are – a matter of public record.

In this case, Hanmi relies on all of Mr. Brackeen's work as contained in the public European Opposition file. Nothing else. AstraZeneca has had it for years and has challenged Mr. Brackeen's work in its own public filings. Mr. Brackeen has not conducted new tests and generated new samples; rather, Mr. Brackeen describes his earlier work and data in his February 19, 2013 report (Ex. A to AstraZeneca March 18, 2013 letter to Court, Brackeen Report at ¶¶ 11-13), which is the subject of AstraZeneca's present *motion in limine.*

AstraZeneca's assertion that there has been a refusal to provide complete discovery concerning this work by Mr. Brackeen is false. (*See* Hanmi's April 9, 2013 letter to Judge Bongiovanni, p. 2.)[2] As Hanmi has repeatedly advised AstraZeneca, Hanmi has produced all responsive documentation in Hanmi's custody and control relied upon by Mr. Brackeen in his February 19, 2013 report. Such materials were produced prior to, and otherwise in connection with Mr. Brackeen's February 19 report. (Hanmi's April 9, 2013 letter to Judge Bongiovanni, p. 2.) Included in these materials is all underlying documentation, including Mr. Brackeen's laboratory notebooks, analytical data and pertinent certificates of analysis. (*See* Ex. 5 to Hanmi April 9, 2013 letter to Court; Ex. A to AstraZeneca March 18, 2013 letter to Court, Brackeen

[2] On March 18, 2013 AstraZeneca filed a letter motion to compel discovery of documentation and samples underlying the work that Mr. Brackeen did for Teva. Hanmi submitted its letter brief in opposition on April 9, 2013. On May 1, 2013 Magistrate Judge Bongiovanni issued a letter order that, among other things, granted AstraZeneca's motion and ordered that Hanmi "either produce the underlying documents or [it] will be precluded from relying on Mr. Brackeen's report." (May 1, 2013 Letter Order at 6.) Following that order, on May 5, 2013, Hanmi again informed AstraZeneca that Hanmi and Mr. Brackeen have produced all materials in their custody and control underlying the work subject of Mr. Brackeen's February 19 report that he is permitted to release pursuant to his commitment to Teva. Accordingly, Hanmi and Mr. Brackeen have fully complied with their discovery obligations. Hanmi further respectfully submits that, for the reasons set forth herein, preclusion of Mr. Brackeen's testimony is unwarranted under the circumstances herein and, insofar as such a motion is necessary, moves for relief from Magistrate Judge Bongiovanni's order to the contrary.

Report, *see, e.g.,* paragraphs 1, 11-13, 23, 24 and 38, Exhibit 2.) AstraZeneca and its experts are more than adequately positioned to respond to the same, and they have done so. AstraZeneca can cross examine Mr. Brackeen at trial, as well as any witness relying on his work, if they choose to do so. Notably, AstraZeneca, as a party to the prior proceedings, is also aware that the actual samples that Mr. Brackeen prepared are the proprietary material of a non-party, Teva Pharmaceuticals, who has not consented to their production here. AstraZeneca was free to take third party discovery of Teva, but elected not to do so. (*See* Hanmi's April 9, 2013 letter to Judge Bongiovanni, p. 2.)

Moreover, the "critical documentation" AstraZeneca complains of has nothing to do with Mr. Brackeen's experimental work, but instead constitutes NMR spectra obtained by Mr. Brackeen in connection with unrelated projects. (AstraZeneca March 18, 2013 letter to Court, p. 2, footnote 1; Ex. 5 to Hanmi April 9, 2013 letter to Court.) AstraZeneca's pursuit of these materials is irrelevant to the issues in this case, and is designed solely to create a basis to preclude Mr. Brackeen's testimony about successfully replicating examples of the DE '455 reference. AstraZeneca's intrusive discovery tactics imposed discovery obligations on Hanmi and Mr. Brackeen falling well outside the scope of discovery permitted by the Federal Rules, and cannot support its present motion to preclude.

B. Reliance By Mr. Brackeen And Other Experts On Mr. Brackeen's Earlier Experimental Work Is Permissible And Will Be Helpful To The Court

Mr. Brackeen's testimony concerning the methodology used and the reproducibility of the DE '455 reference was admitted and affirmatively considered in the earlier European Opposition proceedings. (Decision of the European Patent Office ("EPO") revoking the European Patent 1020461, July 29, 2011; Brackeen Report at paragraphs 43-45.) Notwithstanding AstraZeneca's challenges, Mr. Brackeen's work was credited as a faithful

reproduction of the DE '455 references in Europe, and will be helpful to the Court here for the same reasons.

AstraZeneca has not pointed and cannot point to any analytical gap in the assessment of the fit between Mr. Brackeeen's specific opinions (similarly independently reached by Drs. Kirshning and Hornchen (*see* Ex. 7, Final Report of Dr. Ulrich Hörnchen, April 2010, submitted in the European Opposition proceeding; Ex. 8-9 Test Reports into the Preparation of (R)-Omeprazole and (S)-Omeprazole according to DE 40 35 455 A1, written by Dr. Andreas Kirschning, March 2010 and August 2010, submitted in the European Opposition proceeding; *see also* Ex. 2, Atwood Reply Report at pp. 5-10)), and the data, principles, and methods from which those opinions were derived. *See Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). When fit can be shown, the court should admit the expert's opinion, leaving for the trier of fact the question of whether to credit the testimony. *Id*. ("soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact").

It is improper for AstraZeneca to ask this Court to make premature ultimate conclusions as to the propriety and persuasiveness of the proffered evidence. *See Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.,* 326 F.3d 1333, 1341 (11th Cir. 2003) ("it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence") (citations omitted)). The trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system. *See ID Security Sys. Canada, Inc. v. Checkpoint Sys., Inc.,* 249 F. Supp.2d 622, 692 (E.D. Pa. 2003) (quoting Advisory Committee Notes to amended Rule 702 (the "sufficient facts or data [component of Rule 702] is not intended to authorize a trial court to

exclude an expert's testimony on the ground that the court believes one version of the facts and not the other")).

Mr. Brackeen's testimony responds directly to AstraZeneca's non-enablement allegations and will permit a full understanding of the DE '455 reference (Fed. R. Evid. 702; 4 Weinstein's Federal Evidence § 702.03), as opposed to only analyses selected by, and favorable to, AstraZeneca.

Likewise, Dr. Atwood's testimony concerning Mr. Brackeen's work is entirely permissible and will be helpful to the Court. Experts routinely rely on the work of others, and that reliance is not objectionable as hearsay. Fed. R. Evid. 703. An expert witness may rely upon hearsay information if that information is "of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject." *Id*., *see U.S. v. Mulder*, 273 F.3d 91, 102 (2d Cir. 2001) ("[E]xpert witnesses can testify to opinions based on hearsay or other inadmissible evidence if experts in the field reasonably rely on such evidence in forming their opinions"). An expert appropriately may rely upon reports of others to formulate his opinion, and such reliance is often an ***indicia of reliability***. *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 588 (7th Cir. 2000).

Moreover, AstraZeneca itself recognizes that the work of others may be pertinent and helpful, as its showing of non-enablement is largely based on the testimony and work of others. (*See* Section D, below.)

Hanmi is entitled to present, and the Court should fairly have the benefit of hearing both parties and their experts on this issue.

C. Presentation Of Mr. Brackeen's Testimony At Trial Presents No Prejudice To Astrazeneca

AstraZeneca suggests that reliance by Mr. Brackeen on his own previous work – admitted and considered in a prior proceeding – is improper here simply because such work was done for another party. Such an objection is misplaced. That the work was done for another party is irrelevant and, if anything, only underscores the objective nature of the results and its probative value in this case.

Moreover, AstraZeneca's own expert, Dr. Davies, provided several declarations in the course of the European Proceedings on the very same Brackeen work it seeks to preclude here. (Ex. 6 to Hanmi April 9, 2013 letter to Court, Declaration of Stephen G. Davies dated April 4, 2011; Ex. 7 to Hanmi April 9, 2013 letter to Court, Declaration of Stephen G. Davis dated December 3, 2010.) Dr. Davies has never conducted his own experiments on the Kohl DE '455 patent examples, but rather opines solely on the work of others. And in this action, Dr. Davies has again readily opined on Mr. Brackeen's work, offering many of the same responses he offered in Europe, against other parties. Dr. Davies never stated in any of his expert reports in this case that he needed a sample of Mr. Brackeen's product to complete his analysis, or that he required more data than Mr. Brackeen provided. Nowhere does Dr. Davies state that his opinions were incomplete without the additional information AstraZeneca's counsel argues was withheld, and nowhere did Dr. Davies provide an opinion or conclusion that was contingent on the receipt of additional information. As a result, AstraZeneca is in no way prejudiced by testimony regarding Mr. Brackeen's work years ago, as set forth in his February 19 report.

D. AstraZeneca Should Be Precluded From Relying On Testimony and Evidence For Which It Has Not Produced Samples And Documentation of Experimental Work

Throughout this action, AstraZeneca has consistently relied on the testimony, declarations, and experimental work of third parties in support of its efforts to show that the DE 455 reference is non-enabling. Even Dr. Davies and its other experts rely on declarations and

experimental testing by, *e.g.*, Kohl, Larsson, Senn-Bilfinger, etc. that was carried out years ago in conjunction with the European opposition proceedings. Ironically, AstraZeneca seeks to preclude the same types of materials from Mr. Brackeen that it and its experts expressly rely on in the present case.

There is no serious dispute that the European Opposition proceedings and the testimony of declarants concerning their work has long been a part of this case. (*See* D.I. 113-2, AstraZeneca July 25, 2011, Responses to Hanmi's Invalidity and D.I. 133, 176, 207, AstraZeneca *Markman* briefing incorporating by reference as if fully set forth therein numerous declarations discussing declarant and third party experimental work (see below); *see also* D.I. 87-1, Hanmi's May 25, 2011 Non-infringement and Invalidity Contentions and Ex. 10, Hanmi's Preliminary Claim Construction and Supporting Evidence charts citing EP Oppositions at p. 5 (the entirety of the EP Proceedings as of August 25, 2011 was produced to AstraZeneca on that date (*see* Ex. 11)).) Consistent with that fact, AstraZeneca's papers and expert reports are riddled with citation to the prior testimony and work of its own witnesses and third parties, the documentation and samples of which have not been produced to Hanmi in the course of this action. By way of example:

> AstraZeneca's July 25, 2011 Responses to Hanmi's Invalidity Contentions, incorporating all of the following by reference as though set forth therein (*see* D.I. 113-2, p. 1, n.1; *see also* p. 5, n. 19, 20):
>
> - Andersson Canadian Affidavit, February 17, 2009 (AZ0002251649-775)
> - Larsson EPO Declaration, November 4, 2008 (AZ0002237724-34)
> - Kohl EP Declaration, September 5, 2008 (AZ0002357049-126) ;
> - Kohl Canadian Affidavit, February 13, 2009 (AZ0002252004-78));
> - Senn-Bilfinger EP Declaration, September 23, 2008 (AZ0002237753-58))
> - Lindberg Israel Declaration, August 17, 2004 (AZ0001323665-711));
> - Davies Canadian Affidavit, February 17, 2009 (AZ0002252395-475) Davies EU Declaration April 8, 2009 (AZ0002270355-66) *(id.)*;
> - Davies Denmark Declaration November 17, 2009 (AZ0002279031-95);
> - Davies EPO Declaration December 3, 2010 (AZ0005144446-483);

- Levy EP Opinion (May 19, 2006) and Response submission (December 6, 2006), (AZ0002291364-403; AZ0001543419-423);
- Levy Canadian Affidavit, February 17, 2009 (AZ0002251835-943)

AstraZeneca's *Markman* submissions of November 7, 2011 (D.I. 133), January 6, 2012 (D.I. 176), March 19, 2012 (D.I. 207)

- Andersson Declaration, February 12, 1997 (AZ0005000153-166)
- Larsson Declaration, November 7, 2008 (AZ0002237724-734) D.I. 208-10 - D.I. 208-14
- Senn-Bilfinger Declaration , September 23, 2008(AZ0002237753-758) D.I. 208-1)
- Kohl Declaration, September 5, 2008 (AZ0002357049-065) D.I. 208-2- D.I. 208-7)

AstraZeneca's Expert Reports

- Von Unge EPO Declaration, November 5, 2008 (AZ0002251165- AZ000225121 (Davies Rebuttal Report, p. 28; Bartlett Rebuttal Report, pp. 49-50)
- Von Unge EPO Declaration, August 29, 2012 (Davies Rebuttal Report, p. 60)
- Senn Bilfinger EPO Declaration, September 23, 2008 (Davies Rebuttal Report, pp. 31)
- Davies EU Declaration, April 8, 2009 (AZ0002270356- AZ0002270366) (Davies Rebuttal, p. 31)
- Davies Denmark Declaration, November 16, 2009 (AZ0002279031-AZ0002279095) (Davies Rebuttal Report, p. 31)
- Davies EPO Declaration, December 3, 2009 (Davies Rebuttal Rep. p. 31).
- Davies EPO Declaration, April 4, 2011(Davies Rebuttal Report, p. 31).
- Kohl Canadian Declaration, September 5, 2008 (AZ0002252004-AZ0002252078), Davies Rebuttal Report, p. 31)
- Kohl Declaration, September 5, 2008 (AZ0002525288-AZ0002525307) (Bartlett Report, pp. 48-49)
- Larsson EPO Declaration November 4, 2008 (Davies Rebuttal Report, p.50). (AZ0002237724-AZ0002237734)
- Astra Analytical Report, H 199/18 Magnesium, January 19, 1999 (Byrn Opening Report, p. 40)
- Astra Physicochemical data, H 199/18 magnesium trihydrate, October 14, 1998 (Byrn Opening Report, p. 40)
- Select excerpts von Unge lab notebook, H199/18 (with English translation) AZ0000386558 - AZ0000386559 (Byrn Rebuttal Report, pp. 20, 26)
- Select excerpts von Unge lab notebook, H199/18 AZ0000389819 (Byrn Rebuttal Report, pp. 20, 26)

Under these circumstances, AstraZeneca's motion to preclude reliance on Mr. Brackeen's testimony and prior work, while at the same time intending to proceed with its own reliance on

the prior work and testimony of select others, ***for which original samples and underlying experimental work documentation have not been produced*** to Hanmi is disingenuous and epitomizes trial by ambush. *APP Pharms. LLC v. Ameridose, LLC, 2011* WL 6325975, *1 (D.N.J. Dec. 6, 2011). Such tactics have severely prejudiced Hanmi. If AstraZeneca had not, through its reliance on the work of others throughout this case, effectively concealed its plan to block presentation of EP declarant testimony and work performed by these individuals, Hanmi could have sought to independently have this work replicated and pressed AstraZeneca to do the same for all of the above identified evidence it seeks to rely pursuant to its improper discordant standards. Neither AstraZeneca or any of its witnesses have produced samples that form the basis of all of the experimental work reported upon in the declarations relied upon by AstraZeneca's witnesses. Nor has AstraZeneca produced any data underlying its declarants' experiments beyond what was contained in the public record of the European opposition proceedings. If AstraZeneca's motion *in limine* is granted, fairness demands that same standard apply to AstraZeneca and that it be precluded from relying on, or presenting at trial, the foregoing testimony and evidence.

If the Court is inclined is to grant AstraZeneca's motion to exclude, Hanmi requests that the aforementioned materials and testimony be excluded.

CONCLUSION

For the foregoing reasons, Hanmi respectfully requests that AstraZeneca's motion be denied.

Dated: May 6, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on May 6, 2013, I caused a copy of the foregoing **Hanmi's Opposition To AstraZeneca's Motion in Limine To Preclude Reliance On Evidence of Experiments Performed by Mr. Brackeen For Which Samples and Documentation Have Not Been Produced** to be served upon the following counsel by electronic mail:

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